REMARKS

Status of the Claims

Claims 1-21 and 25-52 were withdrawn from consideration. Claims 22-24 were pending. Claims 22-24 were rejected. No new matter was added to these claims.

Withdrawn Claims 1-21 and 25-52 are canceled herein. Claim 22 has been amended. Claim 23 is canceled.

The 35 U.S.C. §112, Second Paragraph, Rejection

Claim 23 is rejected under 35 U.S.C 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 has been canceled. Therefore, the 35 U.S.C. 112, second paragraph rejection of claim 23 is moot.

The 35 U.S.C. §102, Anticipated, Rejection

Claim 24 stands rejected under 35 U.S.C. 102(b) as being anticipated by Japanese document, **JO9149790-A** (10 June 1997). Applicants respectfully traverse this rejection.

The Examiner states that **JO9149790-A** discloses a serine protease of 241 amino acid residues the same as amino acid residues 615-673 and 675-855 of Applicants' SEQ ID NO: 2, a Tumor Antigen Derived Gene-15 (TADG-15), (page 1 of the translation, sections denoted as claim 1 and claim 2; and **JO9149790-A,** pages 12 and 13, sequence 723. Further, the Examiner states that in section 0025 of the translation "...a specific antibody at the serine protease of this invention..." is disclosed which is same as that claimed. Applicants respectfully disagree.

Claim 24 recites an antibody that is specific for TADG-15 protein. In other words, the antibody is generated against a sequence that is unique to TADG-15 protein and should not bind to other proteins, since the purpose of the antibody in the context of the present invention is to enable detection of TADG-15 protein only. The specification of the present invention teaches that TADG-15 protein comprises domains other than the serine protease

domain (Figure 4). It further teaches that peptide fragments generated from the domains other than the serine protease domain can bind strongly to the HLA molecule based on their longer half lives (Example 9). As one with ordinary skill in this art is well aware, binding to HLA molecule enables a peptide fragment to be expressed on the cell surface. Therefore, these peptide fragments are ideal candidates to design an antibody that serves its purpose in context of this invention.

In contrast, **JO9149790-A** teaches a serine protease of 241 amino acid residues which are similar to the amino acid residues 615-673 and 675-855 of Applicants' SEQ ID NO: 2, TADG-15 protein. These amino acids residues are in the serine protease domain of TADG-15 protein (page 10, line 20). Therefore, the antibody disclosed by **JO9149790-A** would be specific to only the serine protease domain of TADG-15 protein. If one were to design an antibody based on the teachings of **JO9149790-A**, the antibody would bind both the proteins and not bind specifically to TADG-15 protein.

Applicants respectfully disagree, therefore, with the Examiner's contention that the antibody recited in claim 24 is

identical to an antibody theoretically "taught" by **JO9149790-A**. Based on the teachings of **JO9149790-A** alone, one skilled in the art would never be able to anticipate an antibody that is specific to the domains other than the serine protease domain in order to bind specifically to TADG-15 protein. Accordingly, based on these remarks, Applicants respectfully request that the rejection of claim 24 be withdrawn.

The 35 U.S.C. §103 Rejection

Claims 22-24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese document, **JO9149790-A** (10 June 1997). Applicants respectfully traverse this rejection.

The Examiner finds the Applicants' earlier argument about the non-specificity of an antibody for TADG-15 when generated according to the Examiner's methodology as unpersuasive. The Examiner states that the claims do not set forth that the antibody must bind to any particular or unique amino acids residues of the TADG-15 protein but broadly encompass an antibody that is specific for TADG-15 protein which consists of 855 amino acids. While comparing the teachings of accession number

W22987 and the present invention, the Examiner states that since the present invention teaches the importance of serine proteases in cancer, the serine protease domain of TADG-15 also revealed by 241 amino acid fragment of accession number W22987 would be ideal for generation of antibody contained in the kit. Finally, the Examiner states that although the claims recite a kit, there is no positive recitation of the kit ingredients/elements that distinguishes the claim over the references; hence, the claimed subject matter would be obvious over the prior art. Applicants respectfully disagree.

Claim 23 has been canceled. Therefore the 35 U.S.C. 103(a) obviousness rejection of claim 23 is moot. Claim 22 has been amended as described earlier. Amended Claim 22 recites the composition of a kit to detect TADG-15 protein. This kit comprises of: (a) an antibody specific for TADG-15 protein, (b) detectable labels, for detecting the bound antibody.

The Applicants reiterates that the purpose of the antibody in the kit in claim 22 and claim 24 in context of the present invention is to allow specific detection of TADG-15 protein, which can serve as a useful marker for ovarian and other tumor

cells. The specification of the present invention teaches the ability of TADG-15 to serve as a useful marker not only in ovarian tumor cells (Figures 6, 10; Table 2) but also in carcinomas of breast, colon, prostrate and lung (Figure 8). Therefore, it is clear that the antibody will not serve this purpose if it cross-reacts with other proteins.

Accession number **W22987** reveals a 241 amino acid fragment, which encompasses only the serine protease domain of TADG-15 that is a part of the TADG-15 protein. Thus, an antibody specific for TADG-15 protein cannot be generated against these amino acid residues since it will cross-react with both the proteins. Therefore, the Applicants respectfully disagree with the Examiner's contention that the serine protease section of the TADG-15 protein would be ideal in generation of antibody contained in the detection kit.

As the antibody recited in Applicants' claims 22 and 24 of the present invention will be used to determine if the disease is due to TADG-15 protein overexpression, it would be necessary for one with ordinary skill in the art to generate an antibody against a sequence that is unique to TADG-15. In order to accomplish this,

one would have to compare the sequence of TADG-15 with the other published sequences and use the sequence that is not common to TADG-15 and other proteins. Further, the present specification also teaches that some of the peptide fragments generated from domains other than the serine protease domain bind very strongly to HLA molecule and have a longer half-life (Example 9). One skilled in the art can also use this information from the present invention to design antibody specific for TADG-15 protein. None of this is taught by the Japanese document cited by the Examiner. Therefore, claims 22 and 24 recite elements that clearly distinguishes the claims over the reference. Additionally, the kit also comprises of detectable labels to detect the bound antibody, which is described in the specification (page 42, line 1-5, page 42, line 6 -page 43, line 20).

Applicants assert that obviousness requires that the prior art relied upon fairly teach or suggest all the elements of the instant invention and that an incentive or motivation be present in the prior art to produce the claimed invention with reasonable expectation of success in its production. The Applicants have shown that Japanese document does not teach or suggest all elements of the present invention and if one were to rely on its teachings, one

would never be motivated or be able to produce the claimed invention with reasonable expectation of success since the antibody would cross-react with other proteins. Accordingly, based on these remarks and amendments, the Applicants respectfully request the withdrawal of the rejection of claims 22-24.

This is intended to be a complete response to the Office Action mailed February 26, 2004. Applicants submit that the pending claims are in condition for allowance. If any issues remain, please telephone the undersigned attorney of record for resolution.

Respectfully submitted,

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Benjamin Aaron Adler, Ph.D., J.D.
Registration No. 35,423
Counsel for Applicant

ADLER & ASSOCIATES
8011 Candle Lane
Houston, Texas 77071
(713) 270-5391 (tel.)
(713) 270-5361 (facs.)
badler1@houston.rr.co